AF

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	HAEFNER	Examiner:	Kahelin, M.
Application No.:	10/784,478	Group Art Unit:	3762
Filed:	February 23, 2004	Docket No.:	GUID.606PA (03-250)
Title:	HEART SOUNDS FOR SELECTION OF SEPARATED SIGNALS		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence and the papers, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Board of Patent Appeals and Interferences, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on March 28, 2008.

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APPEAL BRIEF

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
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Sir:

This is an Appeal Brief submitted pursuant to 37 C.F.R. § 41.37 for the above-referenced patent application. Please charge Deposit Account No. 50-3581 (GUID.606PA) in the amount of $510.00 for this brief in support of appeal as indicated in 37 C.F.R. § 41.20(b)(2). If necessary, authority is given to charge/credit deposit account 50-3581 (GUID.606PA) any additional fees/overages in support of this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-19 and 30-36 remain pending. Each of the pending Claims 1-19 and 30-36 has been finally rejected by the Examiner's action dated October 10, 2007, from which Appellant appeals. The pending Claims 1-19 and 30-36 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated October 10, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to implantable medical devices and, more particularly, to subcutaneous cardiac sensing and/or stimulation devices employing cardiac signal separation.

Some method embodiments of the present invention are directed to signal separation. (*See, e.g.*, Claim 1, Page 4, Line 27 – Page 5, Line 14, among other locations). Such methods can include detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources. (*See, e.g.*, Page 8, Line 19 –Page 16, Line 22; Page 22, Lines 22-24; Page 24, Lines 7-25; Page 31, Lines 17-27; among other locations). Such method embodiments may further include receiving information associated with a non-electrophysiological cardiac source. (*See, e.g.*, Page 17, Line 26 – Page 18, Line 28; Page 20, Line 8 – Page 21, Line 15; Page 22, Line 25 – Page 23, Line 7; Page 30, Line 10 – Page 31, Line 16; among other locations). Such method embodiments may further include separating a signal from the composite electrical signal using source separation. (*See, e.g.*, Page 25, Line 24 – Page 28, Line 9; Page 28, Line 19 – Page 29, Line 7; among other locations). Such method embodiments may further include verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. (*See, e.g.*, Page 25, Lines 22-24; Page 26, Line 27 – Page 27, Line 6; Page 29, Line 8 – Page 30, Line 9; Page 32, Line – Page 34, Line 22; among other locations).

Such method embodiments may further include that verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart-sound. (*See, e.g.*, Claim 6; Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further include that verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 11, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further comprise determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 12, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further include that the time separation is used to identify a cardiac signal. (*See, e.g.*, Claim 13, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further comprise detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 17, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Embodiments can be directed to an implantable cardiac device. (*See, e.g.*, Claim 30; Page 8, Line 10 – Page 9, Line 8; Page 19, Lines 12-22; Page 22, Line 6-13; Page 24, Lines 3-6; elements 102, 501, 205, 206, 209, 220, 218, 216, 230, 214, 207, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources. (*See, e.g.*, Page 8, Line 19 – Page 16, Line 2; Page 15, Line 13 – Page 16, Line 22; Page 22, Lines 22-24; Page 24, Lines 7-25; Page 31, Lines 17-27; elements 104, 106,202, 207, 214, 204, 203, 504, 506, 502, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for subcutaneously detecting non-electrical cardiac activity. (*See, e.g.*, Page 17, Line 26 – Page 18, Line 28; Page 20, Line 8 – Page 21, Line 15; Page 22, Line 25 – Page 23, Line 7; Page 30, Line 10 – Page 31, Line 16; elements 261, 204, 203, 202, 316, 318, 502, 504, 104, 106, 214, 207, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for separating a signal from the composite electrical signal using source separation. (*See, e.g.*, Page 25, Line 24 – Page 28, Line 9; Page 28, Line 19 – Page 29, Line 7; 204, 203, 210, 202, 205, 206, 209, 314, 316, 318, 302, 306, 310, 312, as well as the descriptions in the specification of the identified elements and elements described

in the cited passages, among other locations). Such embodiments may include means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity. (*See, e.g.*, Page 25, Lines 22-24; Page 26, Line 27 – Page 27, Line 6; Page 29, Line 8 – Page 30, Line 9; Page 32, Line – Page 34, Line 22; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations).

Such embodiments may further include that determining means comprises means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity. (*See, e.g.*, Claim 31, Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Appellant notes that a single structure may correspond to multiple "means" limitations. (*See, e.g., Winbond Electronics Corp. v. International Trade Commission*, 4 Fed.Appx. 832, C.A.Fed., 2001).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 stand rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Re. No. 30,750 to *Diack et al.* (hereinafter "*Diack*").

B. Claims 1-19 and 30-36 stand rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,388,578 to *Yomtov et al.* (hereinafter "*Yomtov*") in view of U.S. Publication No. 2005/0240234 by *Joo et al.* (hereinafter "*Joo*").

C. Claims 14 and 15 stand rejected based on 35 U.S.C. §103(a) as being unpatentable over *Yomtov* in view of *Joo*, as applied to Claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells* (hereinafter "*Wells*").

VII. ARGUMENT

A. The rejection under 35 U.S.C. §102(b) of Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 is improper because Diack fails to teach each of the claimed limitations.

Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Re. No. 30,750 to *Diack et al.* (hereinafter "*Diack*").

As will be explained below, *Diack* does not provide any teachings corresponding to the claimed steps of separating a signal from a sensed composite signal using source separation and verifying that the separated signal is a cardiac signal using the separated signal and non-electrophysiological cardiac source information. The Examiner appears to take the untenable position that *Diack's* band pass filtering to suppress noise in a signal constitutes performing source separation of a composite signal. The rejection is further in error in that *Diack* only discloses assessing two signals to direct therapy, which does not constitute verifying that one of the signals is a cardiac signal using the other signal. These errors in the rejection are further discussed below.

Appellant's independent Claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

Diack discloses a cardiac resuscitator and monitoring apparatus. (Abstract). *Diack's* apparatus senses EKG information (Col. 17, Line 44). The Examiner identifies element 110 of Fig. 14 (element 110 being a band pass filter) and Col. 18, Line 66 as providing a teach of detecting a composite electrical signal and separating a signal from the composite signal using source separation that corresponds to the Claims. Appellant respectfully submits that *Diack's* disclosure as a whole, even in the cited portions concerning a band pass filter, does not provide a teaching of source separation. Appellant respectfully submits that *Diack* does not contemplate using source separation, and describes methods which are different from source separation methods.

Appellant respectfully submits that signal source separation is recognized by those having ordinary skill in the art as a particular and distinct type of signal processing

methodology. Moreover, Appellant respectfully submits that one having ordinary skill in the art would recognize that signal source separation methodologies, such as blind source separation, are characterized by separating composite signals according to their respective sources. (*See, e.g.,* Claim 1, reciting *separating a signal* from the *composite electrical* signal using *source* separation).

Accordingly, signal *source* separation of a composite signal involves separating a signal from the composite signal according to the *source* of the signal. (*See* Page 26, Line 27 – Page 27, Line 4 of Appellant's Specification). None of *Diack's* methods contemplate separating a signal from a composite signal according to the source of the signal consistent with source separation, and none of *Diack's* methods involve source separation in a way that this technique is recognized by one having ordinary skill in the art.

One having ordinary skill in the art would understand that band pass filtering techniques are different from signal source separation techniques. Band pass filtering filters out specified lower and higher frequencies components from a signal. Band pass filtering techniques operate by using the various frequencies in a signal while source separation techniques operate by separating signals according to their respective signal sources.

The "Response to Arguments" section of the Office Action mailed 10/26/2007, which also addresses a different rejection under *Yomtov*, states that:

> the filter technique taught by Diack and the R-wave selector/beat separation taught by Yomtov are "source separation" because they separate desired source signal (the clean ECG signal, and an individual beat signal, respectively) from undesired sources (e.g., skeletal noise, other beats, etc.). Regardless of whether this is performed via manipulation of frequencies or time windowing, the desired source signal is separated from the noise signal. This is a separation of a signal according to its respective source origin. (Pages 5-6).

Appellant respectfully submits that even if a band pass filter is able to filter low and high frequency noise in a signal, such filtering is not conducted according to the source of the

noise, but rather according to frequency. A band pass filter will attempt to filter out low and high frequency noise regardless of noise origin (cardiac or skeletal muscle), and will not filter out noise frequencies within the band frequency being passed. For example, a band pass filter will attempt to filter out high and low frequencies produced by the heart while it also attempts to filter out high and low frequencies produced by skeletal muscle. Likewise, a band pass filter will let mid frequency skeletal muscle signals pass the filter just as it lets mid frequency cardiac signals pass the filter. In this way, band pass filters can suppress signal content having higher and lower frequencies, but as *Diack* acknowledges, band pass filtering does not filter according to noise origin ("band pass filter 110 [is] employed to reduce the effects of muscle potentials and external interferences" - Col. 19, Lines 1-3; emphasis added).

Appellant further submits that such frequency suppression by a band pass filter does not "separate" a signal from a composite signal.

As such, *Diack's* band pass filtering does not separate a signal from a composite signal according to the source of the signal, but rather filters according to frequency without regard to signal source.

The "Response to Arguments" section of the Advisory Action mailed 1/15/2008 states:

> The Examiner is interpreting "source separation" in its broadest reasonable sense, without importing further limitation of the term from Applicant's specification. As such, the grounds set forth in the previous Office Action are maintained; namely that Diack separates a desired signal (a clean ECG signal) from undesired noise surfaces (muscle, EMI, etc.), this constitutes "source separation." (Page 2).

Appellant respectfully submits that the Examiner's interpretation of the Claim term "source separation" as including *Diack's* band pass filtering is in error. Claims in prosecution are given their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." (MPEP § 2111 quoting *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)). Appellant's Specification

discusses signal source separation and provides examples of separating a signal from a composite signal according to the signal source (*See* Page 26, Line 27 – Page 27, Line 4 of Appellant's Specification).

Even if one having ordinary skill in the art did not recognize the term "source separation" as a particular type of signal processing methodology, the ordinarily skilled artesian would know to look past the generic sounding name "source separation" to understand that source separation refers to distinct methodologies. Specific exemplary source separation methodologies are found in the Claims (see Claims 14 and 15) and discussed in the Specification (see Page 26, Line 27 – Page 27, Line 4). As such, to any extent that a hypothetical ordinarily skilled artesian is unsure of what "source separation" refers to, the hypothetical ordinarily skilled artesian would be guided by the Claims and Specification to the correct understanding of source separation as discussed above.

Moreover, to any extent that the hypothetical ordinarily skilled artesian is unsure of what "source separation" refers to, the hypothetical ordinarily skilled artesian would not conclude that band pass filtering is source separation, as even in the descriptive sense of the term "source separation" is not accurately descriptive of band pass filtering. As discussed above, band pass filtering suppresses signal content based on the frequency of the content, agnostic of the source of the content (e.g., high frequency cardiac content will be suppressed along with high frequency skeletal muscle noise, and mid frequency skeletal muscle noise will be passed by the filter, regardless of whether the band pass filter was intended to preserve cardiac signals and suppress skeletal noise).

For the reasons discussed above, one having ordinary skill in the art would not interpret source separation of a composite signal as band pass filtering in light of the Specification. As such, the Examiner's interpretation of *Diack's* band pass filtering as constituting source separation of a composite signal is in error. Therefore, Appellant respectfully submits that *Diack* does not teach separating a signal from the composite electrical signal using source separation, as recited in independent Claims 1 and 30, and the rejection of these Claims should be reversed at least on this basis.

The anticipation rejection of Claims 1 and 30 based on *Diack* also fails to account for the "verification" aspect of these Claims.

Appellant's independent Claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, which is not taught by *Diack,* as discussed below.

Diack's apparatus uses a microphone for sensing respiration sounds. (Col. 19, Lines 39-50, discussing element 122 of Fig. 14, referenced on Page 2 of the Office Action mailed 10/26/2007). "The microphone is employed for ascertaining bodily movement or physical activity, and in particular for ascertaining respiration sound." (Col. 19, Lines 44-47).

Diack's apparatus uses both sensed EKG signals and respiration sounds to select an appropriate therapy from several therapy options. (See Table 1 in the Figures (next to Figs. 4-6), as cited on Page 2 of the Office Action mailed 10/26/2007). Specifically, if normal respiration and EKG patterns are sensed, then no action is taken (first line of Table I); if heart activity is sensed with no respiration, then a defibrillation therapy is applied (second line of Table I); and if heart rhythm and respiration are not sensed (indicating cardiac arrest) then pacing is applied (third line of Table I). (*See* Col. 18, Lines 20-33).

Diack does not disclose that any of the sensed signals are used to verify another signal. Instead, as illustrated by Table I, the similarities and differences between the signals are used to trigger various therapies. Appellant respectfully submits that *Diack's* considering of both EKG and respiration signals in selecting a therapy does not constitute one signal validating another signal, particularly not confirming or rejecting a signal as actually being a separated cardiac signal. Accordingly, Appellant respectfully submits that *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent Claims 1 and 30.

The "Response to Arguments" section of the Office Action mailed 10/26/2007 states that:

> regardless of whether the signals are used to verify whether the separated signals is a cardiac signal (verses non-cardiac) signal, the two signals are used to determine whether the signal is a "normal cardiac signal" (verses an abnormal cardiac signal). Since the normal and abnormal cardiac signals

are examples of "a cardiac signal", as claimed, Diack anticipates the claimed subject matter. (Page 6).

Appellant respectfully submits that the above statement acknowledges that *Diack* just assumes that the collected EKG signal is a cardiac signal and only determines whether the electrical signal represents a normal or abnormal cardiac signal. In terms of anticipating Appellant's claims, it is not sufficient that *Diack* distinguishes between abnormal and normal cardiac signals, as making an assumption that a signal is a cardiac signal (and then assessing the normalcy of the assumed cardiac signal) is essentially the opposite of verifying that the signal is a cardiac signal. Without at least some teaching of a step whereby *Diack* affirmatively verifies that an electrical signal is actually a cardiac signal, and in particular using non-electrophysiological cardiac source information to perform the verification, *Diack* cannot anticipate at least Claims 1 and 30.

As such, Appellant respectfully submits that *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in some variation in each of independent Claims 1 and 30.

For each of the reasons discussed above, Appellant respectfully submits that *Diack* fails to teach each and every element and limitation of at least independent Claims 1 and 30, and therefore cannot anticipate these Claims. Consequently there is an omission of at least one essential element required for a proper anticipation rejection of independent Claims 1 and 30. Dependent Claims 4, 7, 8, 10 16-19, 31, and 34-36 are also patentable over *Diack*, as these claims respectively depend from independent Claims 1 and 30. Consequently there is an omission of at least one essential element required for a proper anticipation rejection of independent Claims 1 and 30 and its associated dependent Claims 4, 7, 8, 10 16-19, 31, and 34-36, and the anticipation rejection of these Claims should be reversed at least on that basis.

1. Dependent Claims 17 and 31.

Appellant's Claim 17 depends from independent Claim 1, and further recites detecting a cardiac condition using the separated signal by performing a correlation between

the separated signal and a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 31 depends from independent Claim 30, and further recites means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity.

As discussed above, *Diack* assess EKG and respiration information independently, where the particular therapeutic course of action is selected depending on the particular combination of results of the assessments. (See Table 1 in the Figures (next to Figs. 4-6); see also Col. 18, Lines 20-33). The Office Action mailed 10/26/2007 cites Table I, as well as the abstract, as the basis of support for the rejection of dependent Claims 17 and 30. (Pages 2-3). Table I does not concern correlating signals, but rather comparing the results of the assessments of the respective EKG and respiration signals. Furthermore, the cited Abstract recites:

> electrodes for ascertaining electrical activity of the heart. A microphone attached to the airway, or a strain gauge applied elsewhere to the patient's body, detects bodily motion, for example respiration. If neither substantial electrical activity nor bodily motion is detected, the patient is considered to be in a cardiac arrest and a pacing impulse is applied to the patient via the aforementioned airway electrodes and/or other electrodes, while if electrical activity is ascertained in the absence of bodily motion, a defibrillating pulse is applied to the patient.

As such, Appellant respectfully submits *Diack* discloses selecting a therapy course of action based on a comparison of independent assessments of patient condition using the signals, and does not teach correlating the signals in time.

For this further reason, the §102(b) rejection of dependent Claims 17 and 31 are unsupported and should be reversed.

B. The rejection under 35 U.S.C. §103(a) of Claims 1-19 and 30-36 is improper because Yomtov fails to teach or suggest each of the claimed limitations, even in view of Joo.

Claims 1-19 and 30-36 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,388,578 to *Yomtov et al.* (hereinafter "*Yomtov*") in view of U.S. Publication No. 2005/0240234 by *Joo et al.* (hereinafter "*Joo*").

Appellant's independent Claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

Yomtov discloses an implantable cardiac monitor. The Office Action mailed 10/26/2007 identifies element 96 (an R wave detector), Col. 17, Line 40, and Figs. 8A-B of *Yomtov* as disclosing separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal. (Page 3).

Appellant respectfully submits that it is unclear which methodology of *Yomtov* is being interpreted as constituting performing source separation of a composite signal. Even so, source separation is not contemplated by *Yomtov*. Appellant refers to the above discussion concerning the understanding of source separation as a particular methodology that separates one or more signals from a composite signal, the separation being performed according to the source of the particular signal. A review of *Yomtov* fails to identify any disclosure of source separation techniques.

Even if one having ordinary skill in the art were to be unaware that "source separation" refers to distinct signal processing methodologies and then ignore the portions of the Claims and Specification explaining and providing examples of these distinct signal processing methodologies, the hypothetical ordinarily skilled artesian would still not conclude that *Yomtov's* methods constitute "source separation" in the generic descriptive sense of the term.

Yomtov's Figure 3 illustrates the cited element 96 (an R wave detector), which is connected with the first and second channels of the multiplexer 74. (Col. 9, Lines 14-30). In addition, the first and second channels of the multiplexer 74 are also coupled to the

pacemaker detector 94 for detecting heart beats initiated by a pace applied to the heart by a pacemaker (i.e. not intrinsic beats). (Id.).

Appellant respectfully submits that distinguishing one type of beat from another (*e.g.*, an intrinsic beat vs. a beat induced by an electrical pace pulse) does not correspond to source separation, because the ECG signals are still from the same cardiac source (Appellant notes that the source of an ECG signal is the heart, regardless of whether from a paced or intrinsic beat). As such, the signals are not separated according to the source of the signal. Furthermore, Appellant respectfully submits that characterizing beat type does not constitute the separation of a signal from a composite signal.

The "Response to Arguments" section of the Office Action mailed 10/26/2007 states:

> Since the signals in both channels are separated by beat, either or both channels are the "separated signal" that the claim language requires. (Page 6).

Appellant respectfully submits that even if two of *Yomtov's* channels represent different types of heart beats (one initiated naturally and the other initiated via pace), each still represents beats from the same heart source. As such, the channels do not carry components of a composite signal separated using source separation methodologies. Furthermore, merely identifying different beat types on two different incoming channels (first and second) does not constitute the separation of a signal from a composite signal.

The "Response to Arguments" section of the Office Action mailed 10/26/2007, while also discussing *Diack* and the §102(b) rejection, states that:

> the R-wave detector/beat separation taught by Yomtov are "source separation" because they separate the desired source signal (the clean ECG signal, and an individual beat signal, respectively) from undesired sources (e.g., skeletal noise, other beats, etc.). Regardless of whether this is performed via manipulation of frequencies or time windowing, the desired source signal is separated from the noise signal. This is a separation of a signal according to its respective source origin. (Pages 5-6).

With regard to time windowing, *Yomtov* states:

> The microprocessor establishes an interrogation window which is wide enough to encompass the QRS complex. To determine the three fiducial points, the microprocessor 92 performs a band pass differentiating function upon the stored ECG data which eliminates the P wave and the T wave from the ECG and performs slope discrimination of the QRS complex. (Col. 14, Lines 24-31).

The failures of band pass filtering in constituting source separation of a composite signal have already been discussed above in connection with Section A of this Appeal Brief.

Furthermore, Appellant respectfully submits that eliminating the P and T waves while keeping the QRS complex of an ECG signal does not constitute *source* separation, as both of the eliminated and preserved waves have the same heart source. As such, they are not separated using source separation.

A PQRST complex represents the electrical cycle of a heart as read by an ECG, each letter referring to a different feature. Appellant notes that independent Claims 1 and 30 each recite some variation of separating a signal from the composite electrical signal using source separation and verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. Considering that in the above quoted portion of *Yomtov* the P and T features are eliminated by windowing the middle QRS features, then the cardiac nature of this alleged "signal separation" must already be known. As such, if a PQRST complex in an ECG signal had been identified and the QRS complex isolated and windowed to eliminate the P and T features, then it would be dubious to "verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information" as further claimed. If one having ordinary skill in the art had already windowed the QRS complex of an identified PQRST complex, then the ordinarily skilled artisan would not verify that the signal with the "separated" QRS complex is indeed a cardiac signal using non-electrophysiological cardiac

source information, as a signal with a PQRST complex is clearly already a known cardiac signal.

As such, the proffered interpretation of *Yomtov* used to support the rejection of Claims 1 and 30 does not correspond to the claimed elements in any way that one having ordinary skill in the art would interpret *Yomtov* and the claimed elements.

For each of the reasons discussed above, Appellant respectfully submits that one having ordinary skill in the art would not interpret *Yomtov's* methods as separating a signal from the composite electrical signal using source separation.

Although the Examiner does not rely on the *Joo* reference to teach or suggest separating a signal from the composite electrical signal using source separation methodologies, a review of the *Joo* reference fails to identify such a teaching or suggestion. Therefore, Appellant respectfully submits that the combination of *Yomtov* and *Joo* fails to disclose separating a signal from the composite electrical signal, as recited in independent Claims 1 and 30.

Appellant's independent Claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

It appears that in addressing the above Claim limitations on Page 3 of the Office Action mailed 10/26/2007, the rejection relies on the following passage of *Yomtov* which discusses Figs. 8A and 8B cited to support the rejection:

> In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS complex in the other channel, it will determine that a valid beat had not been detected.

Appellant respectfully submits that it is unclear from the passage above which of the first and second channels is considered by the Examiner to contain a signal separated from a

composite signal. Even so, neither of these channels is used to verify the other channel as a separated cardiac signal. Although each channel is "verified" as containing a heart beat, *Yomtov* appears to verify each channel independently of the other using thresholds, and not verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. For example, when discussing the verification methods of Figs. 8A-B, *Yomtov* states that:

> if there was noise in the first channel, the microprocessor then proceeds to step 174 to verify that the data stored in the random access memory 84 and obtained from the second channel indicates that there was a valid QRS complex in the second channel. Preferably this is accomplished by discerning if the data stored in the random access memory 84 obtained from the second channel was above a given threshold. (Col. 17, Lines 10-17).

As such, *Yomtov* discloses checking beat detection of a second channel when noise is sensed in the first channel. Appellant respectfully submits that merely switching channels because of noise does not constitute verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. Further, *Yomtov's* verification is performed using a given threshold, not received non-electrophysiological cardiac source information.

Yomtov further discusses the method used in Figs. 8A-B for verifying that a heart beat was detected:

> For example, the microprocessor 92 analyzes the stored data for zero crossings at times which correspond to the ST segment of the ECG wherein, if the heart beat is a valid heart beat, the data would indicate a generally constant level. However, if there was noise in the first channel, the microprocessor will detect zero crossings resulting from signals of changing directions which would not normally occur during this interval. (Col. 16, Lines 61-68).

Accordingly, *Yomtov* discloses independently verifying that data collected on a particular channel is a heart beat by tracking zero crossings and using thresholds, not using one channel to verify that the other channel comprises a cardiac signal. For at least this reason, Appellant respectfully submits that *Yomtov* does not disclose verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30.

The "Response to Arguments" section of the Office Action states:

> Regardless of Yomtov's discussion of thresholds or channel switching at the top of column 17, the cited passage (starting at line 40 of column 17) very clearly indicates that both signals from the first and second channels are used to verify a beat is a valid heart signal. (Pages 6-7).

The cited Col. 17, Lines 40-48 of *Yomtov* states:

> In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS complex in the other channel, it will determine that a valid beat had not been detected. As a result, if in step 178 the microprocessor determines that a valid beat had not been detected, it will set in step 182 another refractory period of, for example, 80 milliseconds.

Appellant respectfully submits that the above passage concerns conditions under which signals will not be verified. The actual verification is performed, as discussed above, independently for each signal using zero crossings and thresholds, not a different signal. (See the flow chart Fig. 8A, where the channel verification steps 174 and 176 using thresholds are performed before step 178, where step 178 asks "IS THIS A VALID BEAT?"). As such,

even if Col. 17, Lines 40-48 of *Yomtov* discloses conditions under which a signal will not be verified because both channels have noise, the Claims recite verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. *Yomtov* simply does not teach or suggest that verifying that a separated signal is a cardiac signal using the separated signal and a different signal. Although step 178 asks "IS THIS A VALID BEAT (Fig. 8A; Col. 17, Lines 40-48), this inquiry does not use one signal to validate that a separated signal is a cardiac signal. Therefore, step 178 does not check the integrity of a separated signal using another signal, as *Yomtov's* assessment of the integrity of the data has already taken place (steps 174 and 176, See Fig. 8A) using thresholds and zero crossings, as discussed above.

For each of the reasons provided above, Appellant respectfully submits that *Yomtov* does not teach or suggest separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal, as contended on Page 3 of the Office Action mailed 10/26/2007 in support of the §103(a) rejection of Claims 1 and 30.

Although the Examiner does not rely on the *Joo* reference to teach or suggest verifying that the separated signal is a cardiac signal using the separated signal and another signal, Appellant respectfully submits that *Joo* does not contain such a teaching or suggestion.

For example, even if *Joo* provides multiple independent methods to detect the presence of a cardiac pulse in the patient ([0100]), such a disclosure does not constitute verifying that a separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. As such, Appellant respectfully submits that *Yomtov* does not teach or suggest verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in some variation in each of independent Claims 1 and 30, even in view of *Joo*.

In support of the notion of combining the respective disclosures of the *Yomtov* and *Joo* references, the Office Action mailed 10/26/2007 states that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Yomtov's invention by utilizing

both an electrophysiological and non-electrophysiological signal to confirm a cardiac pulse to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional transduction means susceptible to different forms of noise, thusly providing highly accurate arrhythmia recognition.

Without acquiescing to the propriety of such a combination, Appellant respectfully submits that such a combination would still fail to arrive at the subject matter claimed in Claims 1 and 30. The proposed combination purports "utilizing both an electrophysiological and non-electrophysiological signal to confirm a cardiac pulse." However, Appellant's Claims 1 and 30 each recite some variation of separating a signal from the composite electrical signal and verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. Even if the proposed combination confirms a cardiac pulse using both an electrophysiological and non-electrophysiological signal, such does not constitute verifying that signal separated from a composite signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. For example, the proposed combination confirms a cardiac pulse, not a separated signal as a cardiac signal.

For each of the reasons discussed above, Appellant respectfully submits that *Yomtov* does not teach or suggest separating a signal from the composite electrical signal and verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in some variation in each of independent Claims 1 and 30. Therefore, these Claims cannot be properly rejected under §103(a) based on this combination of references. Consequently there is an omission of at least one essential element required for a proper §103(a) rejection of independent Claims 1 and 30. Dependent Claims 2-19 and 31-36 are also patentable over *Yomtov* in view of *Joo*, as each of these Claims respectively depend from one of independent Claims 1 and 30.

1. Dependent Claim 6.

Appellant's Claim 6 depends from independent Claim 1, and further recites verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart-sound.

The Office Action mailed 10/26/2007 acknowledges that *Yomtov* does not address non-electrophysiological signals as the second cardiac source signal (Page 3) and relies on *Joo* to provide this disclosure. Appellant respectfully submits that *Joo* does not disclose providing a detection window defined by a start time preceding the temporal location of a peak heart-sound.

For this further reason, the §103(a) rejection of dependent Claim 6 is unsupported and should be reversed.

2. Dependent Claims 11 and 17.

Appellant's Claim 11 depends from independent Claim 11, and further recites verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 17 depends from independent Claim 11, and further recites detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source.

In addressing dependent Claims 11 and 17, the Office Action mailed 10/26/2007 cites Col. 14, Line 24 and Col. 3, Line 23 of *Yomtov*. (Page 4). However, Appellant respectfully submits that these portions of *Yomtov* fail to provide a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source (Claim 11) or detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source (Claim 17). It does not appear that *Joo* provides such a teaching or suggestion. As such, Appellant respectfully submits that these Claims recite elements and limitations not taught or suggested by *Yomtov*, even in view of *Joo*.

For this further reason, the §103(a) rejection of dependent Claims 11 and 17 is unsupported and should be reversed.

3. Dependent Claims 12 and 13.

Appellant's Claim 12 depends from independent Claim 1, and further recites determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 13 depends from intermediary Claim 13, and further recites that the time separation is used to identify a cardiac signal.

In addressing these Claims, the Office Action mailed 10/26/2007 cites Col. 15, Line 23 of *Yomtov*. (Page 4). However, Appellant respectfully notes that this portion of *Yomtov* only concerns a "constant delay stored in memory." (Col. 15, Line 29). This portion of *Yomtov* fails to determine a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. It does not appear that *Yomtov* and *Joo* provide such a disclosure. As such, Appellant respectfully submits that these Claims recite elements and limitations not taught or suggested by *Yomtov*, even in view of *Joo*.

For this further reason, the §103(a) rejection of dependent Claims 12 and 13 is unsupported and should be reversed.

C. The rejection under 35 U.S.C. §103(a) of Claims 14 and 15 is improper because Yomtov fails to teach or suggest each of the claimed limitations, even in view of Joo and Wells.

Claims 14 and 15 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Yomtov* in view of *Joo*, as applied to Claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells* (hereinafter "*Wells*").

Each of Claims 14 and 15 depend from independent Claim 1, directly or indirectly. As discussed above, Claim 1 is not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in this Claim. It does not appear that *Wells* cures all of the identified deficiencies in the §103(a) rejection of Claim 1 based on *Yomtov* and *Joo*. If an independent claim is nonobvious under 35 U.S.C. §103, then any

claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent Claims 14 and 15 are not made obvious by *Yomtov,* even in view of *Joo* and *Wells*.

As such, Appellant respectfully requests withdrawal of the §103(a) rejection of Claims 14 and 15 and notification that these Claims are in condition for allowance.

CLAIMS APPENDIX

1. A signal separation method, comprising:

detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources;

receiving information associated with a non-electrophysiological cardiac source;

separating a signal from the composite electrical signal using source separation; and

verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

2. The method of claim 1, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time and a stop time determined using the non-electrophysiological cardiac source information.

3. The method of claim 2, further comprising detecting a QRS complex within the detection window.

4. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises acoustic emission information.

5. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises a temporal location of a peak heart-sound.

6. (Previously presented) The method of claim 5, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart-sound.

7. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises blood-flow information.

8. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises pulse pressure information.

9. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises pulse oximetry information.

10. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises transthoracic impedance information.

11. The method of claim 1, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source.

12. The method of claim 1, further comprising determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source.

13. The method of claim 12, wherein the time separation is used to identify a cardiac signal.

14. The method of claim 1, wherein the signal is separated from the composite electrical signal using blind source separation.

15. The method of claim 14, wherein the blind source separation comprises an independent component analysis performed on the composite electrical signal.

16. The method of claim 1, further comprising detecting a cardiac condition using the separated signal.

17. The method of claim 1, further comprising detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source.

18. The method of claim 1, further comprising detecting a cardiac arrhythmia using the cardiac signal.

19. The method of claim 18, further comprising treating the cardiac arrhythmia.

20-29. (Canceled)

30. An implantable device, comprising:

means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources;

means for subcutaneously detecting non-electrical cardiac activity;

means for separating a signal from the composite electrical signal using source separation; and

means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity.

31. The device of claim 30, wherein the determining means comprises means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity.

32. The device of claim 30, wherein the determining means comprises means for evaluating the separated signal within a detection window.

33. The device of claim 32, further comprising means for determining a start time to initiate the detection window.

34. The device of claim 30, further comprising means for detecting an arrhythmia using the cardiac electrical signal.

35. The device of claim 34, further comprising means for treating the arrhythmia.

36. The device of claim 30, further comprising means for discriminating cardiac rhythms.

37-48. (Canceled)

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejection of Claims 1-19 and 30-36 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed Claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

Respectfully submitted,

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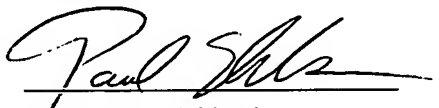

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